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|-------------------------------|------------------------|---------------------|--|
| <b>Notice of Allowability</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                               | 10/014,501             | MERKULOV ET AL.     |  |
|                               | Examiner               | Art Unit            |  |
|                               | Christian L Fronda     | 1652                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS**. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1.  This communication is responsive to Response to 1<sup>st</sup> Office Action dated July 16, 2004.
2.  The allowed claim(s) is/are 4,8,9 and 24-37.
3.  The drawings filed on 14 December 2001 are accepted by the Examiner.
4.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All
  - b)  Some\*
  - c)  None
 of the:
  1.  Certified copies of the priority documents have been received.
  2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3.  Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5.  A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6.  CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a)  including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1)  hereto or 2)  to Paper No./Mail Date \_\_\_\_\_.
  - (b)  including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7.  DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

#### Attachment(s)

1.  Notice of References Cited (PTO-892)
2.  Notice of Draftperson's Patent Drawing Review (PTO-948)
3.  Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4.  Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5.  Notice of Informal Patent Application (PTO-152)
6.  Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_.
7.  Examiner's Amendment/Comment
8.  Examiner's Statement of Reasons for Allowance
9.  Other \_\_\_\_\_.

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## DETAILED ACTION

### *Terminal Disclaimer*

1. The terminal disclaimer filed on July 16, 2004, disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Patent No. 6,294,368 has been reviewed and is accepted. The terminal disclaimer has been recorded.
2. Claims 4, 8, 9 and 24-37 are under consideration in this Office Action.

## EXAMINER'S AMENDMENT

3. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Lin Sun Hoffman on July 22, 2004.

4. The application has been amended as follows:

- In claim 30, line 2, delete the word "peptide" and replace with the word "polypeptide".
- In claim 30, line 2, delete the word "percent".
- Replace claim 31 with the following:  
"An isolated nucleic acid molecule encoding a human metalloprotease polypeptide, said nucleic acid molecule sharing at least 90% homology with a nucleic acid molecule shown in SEQ ID NOS: 1 or 3."

### *Allowable Subject Matter*

5. Claims 4, 8, 9 and 24-37 are allowed.

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6. The following is an examiner's statement of reasons for allowance:  
Applicants' invention is directed toward an isolated nucleic acid molecule from human which encodes a human metalloprotease belonging to the metalloprotease and disintegrin (ADAM) family of proteolytic enzymes. The prior art neither teaches nor suggests an isolated nucleic acid molecule encoding an amino acid sequence of SEQ ID NO:2 or an isolated nucleic acid molecule comprising the nucleic acid sequence of SEQ ID NO: 1 or SEQ ID NO: 3.

In the parent application Serial No. 09/920,048, now US Patent 6, 344,352, claims directed toward an isolated metalloprotease comprising an amino acid sequence having at least 95% identity to SEQ ID NO: 2 were allowed.

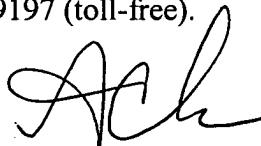
7. The prior art made of record and not relied upon is considered pertinent to applicants' disclosure: Kratzschmar et al. (Accession U41767) teach an nucleic acid having 87.1% identity to SEQ ID NO: 1 and encodes a human membrane anchored metalloprotease-disintegrin protein (see enclosed alignment).

8. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CLF



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SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600